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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,182	08/07/2003	Christopher A. Thierfelder	AMS-161	1760

7590 09/15/2006

Attention: Jeffrey J. Hohenshell
AMS Research Corporation
10700 Bren Road West
Minnetonka, MN 55343

EXAMINER
GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,182	THIERFELDER ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 7/10/2006.

2. In the reply, the Applicant cancelled claims 1-12 and 17-20 and amended claims 13-16.

3. Applicant further amended the Title to make it more descriptive. The Title has been accepted and the objection hereby withdrawn.

4. Applicant further amended claim 14 to obviate the restriction requirement to claim 14 made in the previous rejection. The amendment is found persuasive and claim 14 is hereby not withdrawn and is now pending for examination.

Thus, claims 13-16 remain pending for examination.

Specification

5. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;

(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. **It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.** (Emphasis added)

The Applicant is advised to make the necessary corrections to provide an Abstract that concisely describes the organization/operation of the Applicant's device and the Examiner further recommends focusing on describing the inventive concepts of the Applicant's device.

Claim Notes

6. In reference to claim 13, the Examiner notes that the Applicant may be intending to invoke 35 U.S.C. 112 6th paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.

7. Specifically, in claim 1, the Applicant's recitation of limitation: "storage means for storing a drug" may invoke 35 U.S.C. 112 6th paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.

8. Secondly, in claim 1, the Applicant's recitation of limitation: "metering means for metering a predetermined, effective amount of the drug" may invoke 35 U.S.C. 112 6th

paragraph by using "means for" language reciting function, and not reciting sufficient structure of the means referred to in the specification.

9. The Examiner notes that if the Applicant intends to invoke 35 U.S.C. 112 6th paragraph the Applicant needs to state that on the record and include a specific and detailed description and citation of the exact structure in the specification the means for language is invoking.

10. Finally, claim 1, the Examiner notes that by recitation of reciting sufficient structure of the means referred to in the specification the Applicant has not invoked 35 U.S.C. 112 6th paragraph. The Applicant's recitation of "delivery means for delivering the effective amount of the drug" does not invoke 35 U.S.C. 112 6th paragraph because the Applicant further recites sufficient structure of the means (see claim 1, lns 6-8 including a catheter having multiple drug delivery ports). The Applicant's recitation of "drug delivery path preservation means for resisting fibrous occlusions of the drug delivery ports" does not invoke 35 U.S.C. 112 6th paragraph because the Applicant further recites sufficient structure of the means (see claim 1, lns 11-12 including a substance for resisting the fibrous occlusion).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly amended claim 16 recites the limitation "wherein the drug delivery path preservation means comprises *an effective amount of the substance* for resisting fibrous occlusions in the drug delivery ports" (emphasis added). The Examiner notes that nowhere in the Applicant's specification is "*an effective amount* of the substance for resisting fibrous occlusions" (emphasis added) disclosed. The Applicant clearly discloses an effective amount of the drug to treat a disorder (see [0009, lns 7-9]; [0013, lns 1-5]; [0016]), but does not disclose providing an effective amount of the substance for resisting fibrous occlusions in the drug delivery ports. Thus, newly amended claim 16 presents new matter not originally disclosed and supported in the specification. For purposes of examination, the Examiner has interpreted claim 16 to be wherein the drug delivery path preservation means comprises a substance for resisting fibrous occlusions in the drug delivery ports.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Heil, Jr. (5041107). Heil, Jr. discloses an implantable drug delivery system (10) having a storage means (14; col 5, lns 29-38) for storing a drug; a metering means for

metering a predetermined, effective amount of the drug though a drive electrode (22), a power source (12) and oppositely charged return electrode (26) (col 2, lns 8-56; col 4, lns 16-30); a delivery means for delivering an effective amount of drug comprising a catheter (14) having a longitudinal axis (Fig 1) and having a plurality of drug delivery ports (22, 32, 44) being a plurality of slits (22, 32, 44) that are movable between an open position to delivery the drug to the patient and a closed position (col 3, lns 54-56; col 4, lns 7-9; col 4, lns 16-30); a drug delivery path preservation means for resisting fibrous occlusion of the drug delivery ports comprising a substance for resisting the fibrous occlusion proximate and in the drug delivery ports (col 4, lns 36-46; wherein the Examiner notes that the portion of the catheter body (36) whereby the film or membrane (34) is attached is proximate and structured over the drug delivery port and the film or membrane (34) is a substance that resists formation of fibrous occlusions, such as blood clots via fibrinogen and thrombin).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heil, Jr. in view of Urry (5520672). Heil, Jr. discloses the invention substantially as claimed except for disclosing that the substance for resisting fibrous occlusions comprises poly(glycine-valine-glycine-valine-proline) or poly(GVGVP). Urry teaches that it is known

to have substance for resisting fibrous occlusions comprises poly(glycine-valine-glycine-valine-proline) or poly(GVGVP) (col 7, lns 67-col 8, lns 5) for the purpose of preventing fibrous encapsulation to occur when implanted in a living system (col 7, lns 67-col 8, lns 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substance as taught by Heil, Jr. with the poly(GVGVP) as taught by Urry for the purpose of preventing fibrous encapsulation to occur when implanted in a living system (col 7, lns 67-col 8, lns 5).

Response to Arguments

17. Applicant's arguments with respect to claims 13, 15 and 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER